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Designing a randomized controlled trial to evaluate a community-based narrative intervention for improving colorectal cancer screening for African Americans

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ABSTRACT

Objective: To describe the methodology of a 2-arm randomized controlled trial that compared the effects of a narrative and didactic version of the Witness CARES (Community Awareness, Reach, & Empowerment for Screening) intervention on colorectal cancer screening behavior among African Americans, as well as the cognitive and affective determinants of screening.

Methods: Witness CARES targeted cognitive and affective predictors of screening using a culturally competent, community-based, narrative or didactic communication approach. New and existing community partners were recruited in two New York sites. Group randomization allocated programs to the narrative or didactic arm. Five phases of data collection were conducted: baseline, post-intervention, three-month, six-month, and qualitative interviews. The primary outcome was screening behavior; secondary outcomes included cognitive and affective determinants of screening.

Results: A total of 183 programs were conducted for 2655 attendees. Of these attendees, 19.4% ($N = 516$) across 158 programs (50% narrative; 50% didactic) were study-eligible and consented to participate. Half (45.6%) of the programs were delivered to new community partners and 34.8% were delivered at faith-based organizations. Mean age of the total sample was 64.7 years and 75.4% were female.

Conclusion: The planned number of programs was delivered, but the proportion of study-eligible attendees was lower than predicted. This community-based participatory research approach was largely successful in involving the community served in the development and implementation of the intervention and study.

1. Introduction

Colorectal cancer (CRC) is a leading cause of cancer morbidity and mortality in the United States [1]. African Americans are at higher risk for both the incidence of and death from CRC than any other ethnic/racial group [1], with 22% higher incidence and 49% higher mortality than their white counterparts. CRC screening can reduce CRC incidence and mortality, but adherence to screening guidelines remains lower than national goals and rates for other screening modalities [2], especially for underserved populations [3].

Several complex and multilevel factors influence CRC screening adherence [4–6], but screening ultimately requires a decision to screen made by an individual. Health decision-making models suggest these decisions are influenced by both cognitive and affective/emotional factors [7–11]. Using colonoscopy screening as an example, lack of knowledge is a cognitive barrier, and negative affective associations (e.g., embarrassment and disgust about the procedure, or fear about pain and test results) are affective barriers that are associated with lower screening rates. Studies suggest affective associations may be particularly important determinants of screening behaviors [11,12],

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and therefore an important, but underexamined, target for CRC screening interventions.

Narrative communication strategies may provide an effective approach for interventions addressing the affective determinants of behavior. Narratives are first-person accounts of one's personal experience with a behavior or health threat [13]. In the realms of diet, exercise, and cancer screening, narrative interventions, such as survivor stories and testimonials, have effectively reduced cognitive and affective barriers, and increased engagement in or intentions to engage in the target behavior [14–17].

1.1. The Witness CARES Intervention

The intervention described here, The Witness CARES (Community Awareness, Reach, & Empowerment for Screening) Project, is a culturally competent, community-based education program developed with the goal of increasing CRC screening in African American adults, thus advancing the goal of reducing racial/ethnic disparities in CRC incidence and mortality. To achieve this goal, the intervention targeted both cognitive and affective predictors of CRC screening using a culturally competent, narrative or didactic communication approach. It was designed to be delivered in a community setting, thus bypassing several system-level barriers (see theoretical framework illustrated in Fig. 1).

This paper describes the innovative methodology of a randomized controlled trial (RCT) comparing outcomes of a narrative-based Witness CARES program to that of a traditional, didactic educational version. Recognizing the need for community expertise and engagement, all phases of the study, including trial development, patient recruitment, and data quality monitoring, were conducted in accordance with a community-based participatory research (CBPR) process. The primary goal was to increase African Americans' engagement in CRC screening by targeting changes in cognitive and affective determinants of screening (results forthcoming). We hypothesized that the narrative program would increase screening intentions and behavior relative to the didactic intervention, which served as the standard of care control, and that this increase would be mediated by changes in both affective and cognitive screening predictors (see Hypotheses).

2. Methods

2.1. Overview

This intervention used an RCT with pre-post assessments of decision-making factors and behavioral outcomes to examine the effect of the Witness CARES narrative program compared to the didactic, standard of care control program. Programs were conducted in upstate/western New York (WNY) and New York City (NYC) and the institutional review boards for each site approved all study procedures and materials prior to data collection.

2.2. Hypotheses

Given the literature supporting the effectiveness of narrative communication in community-based group settings as a means of increasing screening behavior, we hypothesized the following:

H1. The narrative-based Witness CARES program will be more effective than the didactic program at increasing positive affective and cognitive evaluations, and reducing negative affective and cognitive evaluations, of CRC screening.

H2. The narrative-based Witness CARES program will increase screening intentions and behavior (having had or scheduled a colonoscopy or performed a stool test 6-months post-intervention) more than the didactic program.

H3. Compared to the didactic programs, the narrative programs will evoke a greater increase in participants' discussions with their primary care provider about CRC screening, including asking for screening referrals and initiating these discussions themselves. Given these discussions are a preliminary step to engaging in screening behavior, the narrative programs' effect on this outcome will elucidate one potential mechanisms through which it increases screening rates.

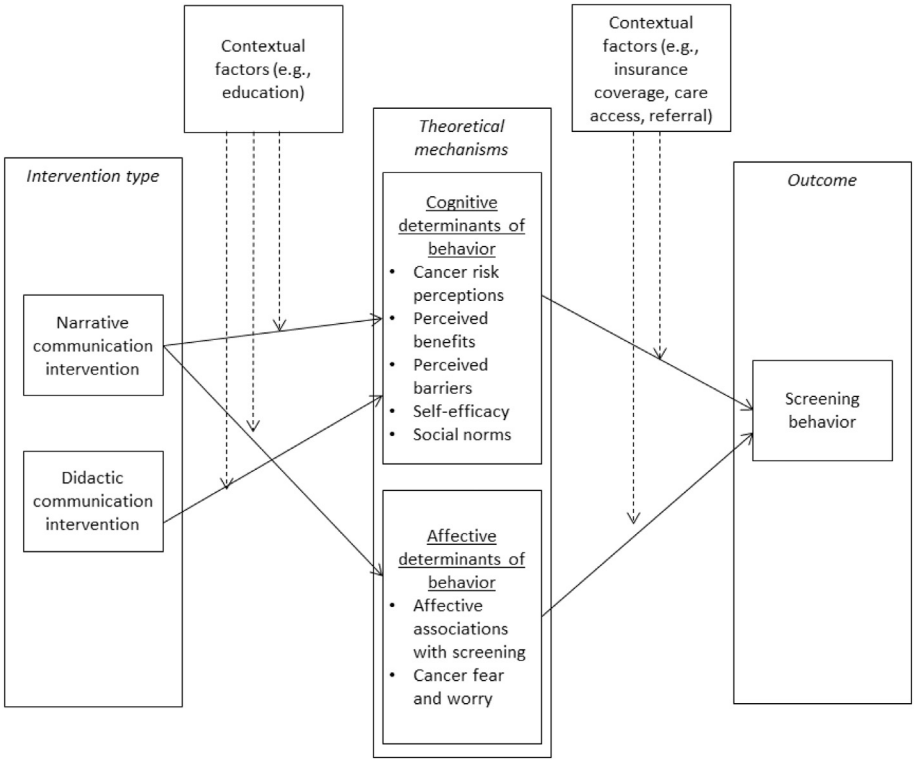

Fig. 1. Theoretical framework.